K04 1581

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Page 1 of 6

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ComPACS 510 (k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21 CFR 807.92(a).

807.92(a)(1)

Submitter Information

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Phone:	+39 0103071634
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Contact Person:	Maria Rosa Bellisario
Date:	May 20, 2004

807.92(a)(2)

Device Name

Trade Name:	ComPACS, ComPACS Components
Common Name:	ComPACS
Classification Name(s):	System, Image Processing
Classification Number:	892.2050
Product Code:	LLZ

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K041591
Page 1 of 6

807.92(a)(3)

ComPACS 510 (k) Summary – Predicate Device(s)

Manufacturer:	AETMED, S.P.A. VIA SIFFREDI 58 GENOVA, I-16153, ITALY
Tradename:	AETMED IMAGE PROCESSING SOFTWARE
510(k) Number:	K012093
Manufacturer:	PROBLEM SOLVING CONCEPTS, INC. 8020 CASTLEWAY DR. INDIANAPOLIS, IN 46250, USA
Tradename:	PROSOLV® CARDIOVASCULAR
510(k) Number:	K023112
Manufacturer:	TOMTEC IMAGING SYSTEMS, GMBH EDISONSTRASSE 6 UNTERSCHLEISSHEIM, D-85716, GERMANY
Tradename:	IMAGE-ARENA
510(k) Number:	K040546
Manufacturer:	INTELLIGENT IMAGES SRL VIALE CEMBRANO 4C/4 GENOVA, I-16148, ITALY
Tradename:	IN-VISION VIEW WITH MEASUREMENTS MODULE
510(k) Number:	K022940

Additional substantial equivalence information is provided in the following substantial equivalence section.

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807.92(a)(4) **ComPACS 510 (k) Summary - Device Description**

ComPACS is a software device intended to be used by qualified medical professionals, after proper installation on an appropriate hardware platform, for capturing, archiving, retrieving, viewing, printing, processing, analyzing, reporting and communicating medical digital studies such as cardiac catheterization, echocardiography or general radiological studies.

ComPACS is a modular software device composed of different software modules operating in synergy and each responsible of different functions. The modules can be distinguished into general review station components, analysis components, reporting components, server components and gateway components.

General Review Station Components

ComPACS viewer constitutes the basic module for a review station providing viewing capabilities and retrieving capabilities from DICOM files in removable media. ComPACS Archive introduces archiving and retrieving of studies on the local review station. ComPACS Net Client allows a review station to archive and retrieve studies from a ComPACS Net Archive or from a third party DICOM compliant PACS. ComPACS Multi-Media extends ComPACS Archive to import and archive multi-media files with conversion to the DICOM format. ComPACS audio introduces digital audio management capabilities.

Analysis Components

The review station can be extended with different analysis modules. ComPACS QCA and ComPACS LVA provide respectively quantitative coronary analysis and left ventricular analysis on angiographic images. ComPACS Echocardiac, ComPACS Stress Echo provide different echo analysis features. ComPACS IVUS allows measurements and longitudinal image reconstruction on IVUS images.

Reporting Components

ComPACS Reporting allows report creation and management. This component can be further subdivided into subcomponents in relation to the different type of reports: Generic, Echocardiac, angiographic, etc. ComPACS Dictation extends the reporting module to allow for audio dictation into the report.

Server Components

ComPACS Net Archive is the basic server modules allowing archiving and retrieving of studies from remote workstations equipped with a ComPACS Net Client module. ComPACS Security introduces user activity logging and user rights profiles management. ComPACS Storage Server provides DICOM network storage services as SCP. ComPACS Dictation Server manages the dictated reports and transfers them to an external transcription service.

ComPACS Small Business Server and ComPACS Enterprise Server provide DICOM network services for small and large size networks respectively.

Gateway Components

ComPACS Recorder is a device capable of digitizing analog video signals and converting to DICOM compliant files for storage on media or network transfer to a DICOM server.

K041051
page 4 of 6

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807.92(a)(5)

ComPACS 510 (k) Summary - Intended Use(s)

ComPACS is a software device intended to be used by qualified medical professionals, after proper installation on an appropriate hardware platform, for capturing, retrieving, viewing, printing, processing, analyzing, reporting and communicating medical digital studies such as cardiac catheterization, echocardiography or general radiological studies.

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807.92(a)(6)

ComPACS 510 (k) Summary -Substantial Equivalence

ComPACS is substantially equivalent to Aetmed Image Processing Software, Prosolv® Cardiovascular, and Image-Arena. While there are some technological differences between ComPACS and the substantially equivalent devices, these differences do not affect the safety or effectiveness of the new device.

The primary difference between ComPACS and these three substantially equivalent devices is in the image management flexibility and DICOM format support. ComPACS appears to have a more advanced multi-window and multi-monitor image management and a wider support of the DICOM format in the different color encoding and compression options as well as a greater tolerance to slightly non compliant files. These features add to the safety and effectiveness of the device.

While all the devices are capable of performing analysis on different type of image modalities, ComPACS appears to provide analysis support for a wider set of modalities than any of the single equivalent devices although there no modality for which ComPACS provides unique support. This adds to the effectiveness of the device without compromising the safety.

Another difference between ComPACS and these three substantially equivalent devices is the management of audio data and report dictation, adding to the effectiveness of the device.

ComPACS is also substantially equivalent to In-Vision View with Measurements Module, an stand-alone software from Intelligent Images. The substantial equivalence is related to the ComPACS viewer and ComPACS IVUS components for the viewing and measurement functions on IVUS images. The only significant difference is ComPACS ability to support multi-window and multi-monitor display.

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ComPACS 510 (k) Summary

807.92(b)(1)(2)

Non Clinical Tests

ComPACS performance is substantially equivalent to Aetmed Image Processing Software, Prosolv® Cardiovascular, and Image-Arena. While there are some technological differences between ComPACS and the substantially equivalent devices, these differences do not affect the safety or effectiveness of the new device.

ComPACS image storage, query and retrieval, including DICOM network connectivity, have been tested using image sets from different imaging devices from different manufactures. The primary differences between ComPACS these three substantially equivalent devices appears to be in the wider support of both DICOM formats and proprietary formats (DSR-TIFF, DEFF) and in a wider range of search criteria for study query purposes. These features add to the safety and effectiveness of the device.

ComPACS performance is also substantially equivalent to In-Vision View with Measurements Module, a stand-alone software from Intelligent Images with an added support in ComPACS multi-window and multi-monitor display. These features add to the safety and effectiveness of the device.

807.92(b)(3)

Non Clinical Tests - Conclusions

The nonclinical and clinical tests demonstrate that ComPACS is substantially equivalent to Aetmed Image Processing Software, Prosolv® Cardiovascular, Image-Arena and In-Vision View with Measurements Module. The tests show that ComPACS is as safe, as effective and performs as well or better than such legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2004

Intelligent Images S.r.l. (MediMatic)
% Mr. Daniel W. Lehtonen
Staff Engineer
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K041581
Trade/Device Name: ComPACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: June 12, 2004
Received: June 14, 2004

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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ComPACS 510 (k) Summary - Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Intelligent Images S.r.l.

510(k) Number (if known): K041581

Device Name: ComPACS

Indications For Use:

ComPACS is a software device intended to be used by qualified medical professionals, after proper installation on an appropriate hardware platform, for capturing, retrieving, viewing, printing, processing, analyzing, reporting and communicating medical digital studies such as cardiac catheterization, echocardiography or general radiological studies.

The software can be used in a variety of network configurations ranging from a stand-alone workstation to a network of workstations connected to a ComPACS server configuration. DICOM compatible imaging devices can transfer studies directly to the ComPACS archive using DICOM network protocols or DICOM removable media.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

Intelligent Images S.r.l.

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

Prescription Use ✓
(Per 21 CFR 801.109)